

REMARKS

In the Final Action dated April 28, 2003, claims 33-38 are pending and are under consideration. Claim 36 is allowed. Claims 33-35 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by U.S. Patent No. 5,032,396 to Williams (July 16, 1991). Claims 33-34 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Sigma's Catalog (January 1992), Product No. T-5028 or T-5153 (*Nature* 321, 441 (1986)) or A-7907 (*PNAS USA* 79:1443 (1982)). Claims 37-38 are rejected under 35 U.S.C. §103(a) as allegedly obvious over Suggs et al. (*PNAS USA* 78(11): 6613-6617, 1981) in view of Williams. Claims 33-35 and 37-38 are further rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to satisfy the written description requirement. The specification and the claims are also objected to allegedly for failing to fully comply with sequence rules.

This Response addresses each of the Examiner's rejections and objections. Applicants therefore respectfully submit that the present application is in condition for allowance or at least in better condition for appeal. Favorable consideration of all pending claims is therefore respectfully requested.

The Examiner has objected to the specification for allegedly presenting on pages 9, line 33, page 10, lines 7, 11 and 27 and page 11, line 10, amino acid sequences without references to sequence identifiers. In addition, the Examiner has pointed out that Figure 9b, Figure 10 and claims 33-34 present sequences which are not identified by sequence identifiers.

Applicants respectfully submit that the sequence, -X1-X2-Asn-Asp, presented on page 10, line 7 and page 11, line 10, is presently identified by SEQ ID NO: 15.

Applicants respectfully direct the Examiner's attention to the Amendment dated November 7, 2002, by which Applicants have inserted the sequence identifier of SEQ ID NO: 15 in the specification.

With respect to the structure formula, R1-X1-X2-Asn-Asp-R2, presented on page 9, line 33, and page 10, lines 11 and 27, Applicants respectfully submit that the central segment "X1-X2-Asn-Asp" is already represented by SEQ ID NO: 15. As described at page 10, lines 14-24, R1 and R2 can be a D or L amino acid, a peptide, a polypeptide, a protein, and can also be a non-amino acid moiety or molecule such as an alkyl, substituted alkyl, alkenyl, substituted alkenyl, acyl, dienyl, arylalkyl, arylalkenyl, aryl, substituted aryl, heterocyclic, substituted heterocyclic, cycloalkyl, substituted cycloalkyl, halo, haloalkyl, nitro, hydroxy, thiol, sulfonyl, carboxy, alkoxy, aryloxy and alkylaryloxy group and the like. Therefore, Applicants submit that "R1-X1-X2-Asn-Asp-R2", as presented on page 9, line 33, and page 10, lines 11 and 27, is not strictly an amino acid sequence which can be properly included in a Sequence Listing.

As to the sequences presented in Figure 9b and Figure 10, Applicants have amended the descriptions of these drawings at page 18 to insert the corresponding sequence identifiers.

With respect to the sequences presented in claims 33-34, these claims have been amended to insert the sequence identifiers, SEQ ID NO: 17 and SEQ ID NO: 18. Applicants are also providing a substitute paper copy and a computer-readable copy of the Sequence Listing to include SEQ ID NOS: 17-18. A statement under 37 C.F.R. §1.821(f) is also attached hereto.

No new matter is introduced by the foregoing amendments. It is therefore respectfully submitted that the objection to the specification and the claims under the Sequence Rules is overcome. Withdrawal of the objection is therefore respectfully requested.

Claims 33-35 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by U.S. Patent No. 5,032,396 to Williams (July 16, 1991). It is observed that Williams teaches the murine IL-7 protein, the sequence of which includes "Gln-Lys-Lys-Asn-Asp-Ala".

Applicants respectfully submit that original claims 33-35 are written with the "consisting of" language, and that the claimed peptide has one amino acid residue on at least one side of the X₁-X₂-Asn-Asp motif, where X₁ and X₂ each represent an amino acid residue. Nowhere does Williams teach or suggest the peptides of original claims 33-35.

Applicants further respectfully submit that, by way of the instant amendment, claims 33-34 have been amended to further define X₁ and X₂ as Lysine residues. Claim 35 has been canceled without prejudice. Williams does not teach or suggest the peptides of claims 33-34, as presently recited.

Accordingly, it is respectfully submitted that the rejection of claims 33-35 under §102(b), as allegedly anticipated by Williams, is overcome. Withdrawal of the rejection is therefore respectfully requested.

Claims 33-34 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Sigma's Catalog (January 1992), Product No. T-5028 or T-5153 (*Nature* 321, 441 (1986)) or A-7907 (*PNAS USA* 79:1443 (1982)).

Applicants respectfully submit that the peptides of claims 33-34, as presently amended, consist of the sequence R1-Lys-Lys-Asn-Asp-R2. Sigma's Catalog does not disclose any peptide that contains the sequence segment of Lys-Lys-Asn-Asp. Therefore, it is respectfully submitted that Sigma's Catalog does not teach the peptides as presently claimed. Withdrawal of the rejection of claims 33-34 under §102(b) based on Sigma's Catalog is respectfully requested.

Claims 37-38 are rejected under 35 U.S.C. §103(a) as allegedly obvious over Suggs et al. (*PNAS USA* 78(11): 6613-6617) in view of Williams.

Applicants respectfully submit that claim 38 has been canceled by way of the instant amendment, rendering the rejection thereof moot. Claim 37 is directed to an isolated nucleic acid molecule encoding the peptide according to any one of claims 33-34 or 36.

As submitted above, Williams does not teach or suggest the peptides of claims 33-34, as presently recited. Suggs et al. do not cure the deficiencies of Williams. Suggs et al. merely teach isolation of the appropriate DNA sequence coding for a particular protein. Therefore, it is respectfully submitted that Suggs et al. and Williams, alone or in combination, do not teach or suggest the isolated nucleic acid molecule of claim 37.

Accordingly, the rejection of claims 37-38 under 35 U.S.C. §103(a) is overcome. Withdrawal of the rejection is therefore respectfully submitted.

Claims 33-35 and 37-38 are rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular, the

Examiner alleges that the specification does not describe in clear terms even a single or representative number of species of the genus.

Applicants previously submitted that the specification describes the general structure of the claimed protease sensitive peptide genus: R1-X1-X2-Asn-Asp-R2, and that the specification further provides an example of a protease sensitive peptide of SEQ ID NO: 3, which is cleaved at six sites to produce seven peptides.

The Examiner now argues that the seven peptides are merely the product of cleavage from SEQ ID NO: 3, and are not examples of protease sensitive peptides.

Applicants respectfully submit that the seven peptides as set forth in SEQ ID NOS: 4-10, are not themselves examples of a protease-sensitive peptide, presently claimed. However, the protein having SEQ ID NO: 3, which contains seven copies of the cleavage motif, R1-X1-X2-Asn-Asp-R2, is cleaved at each of these sites. Therefore, the protein having SEQ ID NO: 3, and apparently various portions of this protein, are sensitive to cleavage by protease, and therefore provide convincing support for the claimed protease-sensitive peptide.

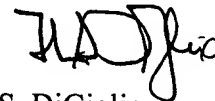
Applicants further respectfully submit that the specification clearly describes the presently claimed protease sensitive peptide genus which consists of "R1-X1-X2-Asn-Asp-R2", wherein X1 and X2 are both Lys, and at least one of R1 or R2 represents one amino acid residue. See pages 10-12 of the specification. Applicants respectfully submit that the law does not require a reduction to practice of every aspect of the claimed invention for the purpose of satisfying the written description requirement under 35 U.S.C. §112, first paragraph. Applicants respectfully submit that the claimed protease-sensitive peptide is adequately described in the specification, and that the specification

clearly conveys to those skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Accordingly, the rejection of Claims 33-35 and 37-38 under 35 U.S.C. §112, first paragraph, is overcome. Withdrawal of the rejection is therefore respectfully submitted.

In view of the foregoing, it is respectfully submitted that the present case is in condition for allowance, which action is earnestly solicited

Respectfully submitted,



Frank S. DiGiglio
Registration No. 31,346

SCULLY, SCOTT, MURPHY & PRESSER
400 Garden City Plaza
Garden City, New York 11530
(516) 742-4343

FSD/XZ:ab

Encls.: Sequence Listing (substitute paper and substitute CRF)
Statement Under 37 C.F.R. §1.821(f)